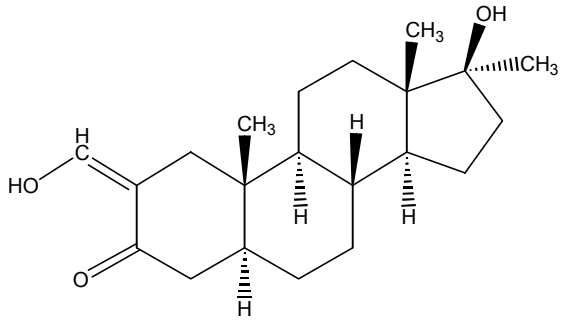
OXYMETHOLONE
CAS No. 434-07-1
First Listed in the *First Annual Report on Carcinogens*



CARCINOGENICITY

Oxymetholone is *reasonably anticipated to be a human carcinogen* based on limited evidence of carcinogenicity in humans (IARC V.13, 1977; IARC S.4, 1982). Ten cases of liver tumors have been reported in patients with blood disorders treated for long periods with oxymetholone alone or in combination with other androgenic drugs; however, a causal relationship cannot be established. The increased risk of liver tumors could be related to hepatic damage known to be caused by oxymetholone. Alternatively, patients with congenital anemias may be at higher risk of developing these tumors, and this risk may become manifest during the extended survival resulting from oxymetholone treatment (IARC V.13, 1977; IARC S.4, 1982).

There are no data available to evaluate the carcinogenicity of oxymetholone in experimental animals (IARC S.4, 1982).

PROPERTIES

Oxymetholone is a white to creamy white crystalline solid that is practically insoluble in water, soluble in ethanol, dioxane, and ether, and very soluble in chloroform. Oxymetholone is available in the United States as an NF grade containing 97%-103% active ingredient on a dried basis, with a maximum of 3% foreign steroids or other impurities. It is stable in air.

USE

Oxymetholone is a synthetic anabolic-androgenic steroid hormone having actions similar to those of the male hormone testosterone. It is used primarily in clinical therapy to maintain a positive nitrogen balance. It can be used to reverse excess excretion of calcium and nitrogen resulting from corticosteroid therapy, prolonged immobilization, and other diseases characterized by catabolism and tissue depletion. It is used to promote weight gain, to counteract weakness and emaciation resulting from debilitating diseases, and after serious infections, burns, trauma, or surgery. It is marketed as a human prescription drug for the treatment of anemias caused by deficient red cell production. It has been used as an anabolic steroid for small animals. Formerly, oxymetholone was used for adjuvant therapy for senile and postmenopausal osteoporosis (IARC V.13, 1977).

PRODUCTION

There are no current production data for oxymetholone. There is no evidence that it has ever been produced commercially in the United States. The Chem Sources USA directory identified two suppliers of oxymetholone in 1986 (Chem Sources, 1986). No separate export or import data are available; however, the United States imported over 3 million lb of all anabolic agents and androgens in 1985 (USDOC Imports, 1986). In 1981, the USITC reported that oxymetholone was imported, but no specific import data were available. The 1979 TSCA Inventory and CBI Aggregate reported no production or import data for oxymetholone in 1977. In 1977, U.S. sales of oxymetholone were estimated to be less than 44 lb annually (IARC V.13, 1977).

EXPOSURE

The primary routes of potential human exposure to oxymetholone are ingestion and dermal contact. The FDA's Center for Drugs and Biologics estimated that 50,000-100,000 patients formerly were treated each year with oxymetholone for postmenopausal osteoporosis. The usual adult dose for anemias due to deficient red cell production is 1 to 5 mg/kg body weight per day. A minimum trial of 3 to 6 months should be given. Health professionals are potentially exposed to oxymetholone while dispensing or administering the tablets. Potential occupational exposure may occur during the formulation and packaging of the pharmaceuticals. The risk of potential occupational exposure is low, since the compound is not produced in the United States. The National Occupational Exposure Survey (1981-1983) indicated that an estimated 742 total workers, including 359 women, potentially were exposed to oxymetholone (NIOSH, 1984).

REGULATIONS

Because oxymetholone is a pharmaceutical and used in low quantities relative to other compounds, it is of little regulatory concern to EPA. There may be a small pollution problem relative to hospital wastes. Since there is no evidence of domestic manufacture, it is unlikely that EPA will investigate sources for possible regulation. FDA reduced the list of approved uses of oxymetholone in 1972, and again in 1983. Since 1977, FDA has required warning labels that indicate possible adverse effects. OSHA regulates oxymetholone under the Hazard Communication Standard and as a chemical hazard in laboratories. Regulations are summarized in Volume II, Table B-116.